Remarks

Claims 5-7, 13, and 17-19 are pending. Claim 6 is allowed. Claims 7, 18, and 19 are hereby amended. Support for the amendments to claims 7, 18 and 19 is at page 58, lines 16-24.

This response discusses two office actions since the Examiner maintained the rejection of claim 7 for reasons of record in the previous office action. The previous office action is referred to herein as "the "1/16/01 Office Action." The current office action is referred to herein as "the 7/27/04 Office Action."

Response to rejection of claims 5, 13, and 17 under 35 U.S.C. § 112, first paragraph, written description.

The Examiner rejected claims 5, 13, and 17 for including new matter because the Examiner found "no literal support anywhere in the originally filed specification or claims for the new limitation." The Examiner stated that "each of the claims comprises a limitation that the nucleic acid of the invention hybridizes under stringent conditions to a nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49-387." (7/27/04 Office Action at 3).

The limitations "nucleotide sequence of SEQ ID NO: 1" and "hybridizes under stringent conditions" were added to the subject claims by amendment. The originally filed specification contained the nucleotide sequence of SEQ ID NO: 1 in the sequence listing. Hybridization under stringent conditions is described at page 15, lines 11-23 of the originally filed specification. Therefore, "nucleotide sequence of SEQ ID NO: 1" and "hybridizes under stringent conditions," as recited in the subject claims, are not new matter.

The feature "a second nucleic acid that consists of the complement of the nucleotide sequence of SEQ ID NO: 1 from nucleotide 49 to nucleotide 387," was added to the subject claims by amendment. The nucleotide range 49-387 of SEQ ID NO: 1 is the coding sequence within SEQ ID NO: 1 which encodes the TCL-1 protein of SEQ ID NO: 2. SEQ ID NO: 1 presents the amino acid sequence that corresponds to the coding region of SEQ ID NO: 1 DNA immediately below the coding region of the DNA. The depiction of SEQ ID NO:1 in the

sequence listing clearly shows that the codon for the first amino acid starts at nucleotide 49, and that the codon for the last amino acid ends at nucleotide 387. Since nucleotides 49-387 are shown in the sequence listing as the portion of SEQ ID NO: 1 coding for the TCL-1 polypeptide of SEQ ID NO: 2, the nucleotide range recited in the claims is not new matter.

Because the originally filed specification literally supports all of the elements of the subject claims, the new matter rejection is inappropriate. The Applicants request withdrawal of this rejection.

Response to rejection of claims 18-19 under 35 U.S.C. § 112, first paragraph, enablement.

The Examiner rejected the subject claims as not enabled, saying that "there is no teaching how one would go about constructing [the claimed protein] and then use the polypeptide to generate antisera that would necessarily recognize the human TCL-1 protein" (7/27/04 Office Action at 4). While Applicants do not agree with the Examiner, in an earnest effort to advance prosecution of the instant application, Applicants have amended claims 18 and 19. Claims 18 and 19 have been amended to further characterize the isolated protein as binding an antibody which also binds the TCL-1 protein of SEQ ID NO: 2.

Given the teaching in the specification of how to make and use protein expression systems (page 20, line 17 to page 26, line 7), and SEQ ID NO: 2, one of ordinary skill in the art could readily synthesize a protein comprising a sequence that has 70 % identity with SEQ ID NO: 2 over at least 25 amino acids. One of ordinary skill in the art could readily test whether that protein binds an antibody which also binds the TCL-1 protein of SEQ ID NO: 2 using the teachings of the specification for making anti-TCL-1 antibodies (page 58, lines 16-24) and immunoassays (page 40, line 25 to page 41, line 8). One of ordinary skill in the art would readily understand that the anti-TCL-1 antibodies needed to test the claimed proteins can be produced given the teaching of the specification that such an antibody was produced (page 28, lines 32-36). Therefore, one of ordinary skill in the art would be able to use the teachings of the specification to construct and test the claimed proteins, without undue experimentation.

Since antibodies bind to specific epitopes, one skilled in the art would readily understand that proteins that bind the same antibody must share similar epitopes. Claims 18 and 19 require that the claimed proteins bind an antibody which also binds the TCL-1 protein of SEQ ID NO: 2. Thus, one of ordinary skill in the art would readily understand that the claimed compounds share a similar epitope with the TCL-1 protein of SEQ ID NO: 2. One skilled in the art would readily understand that since the claimed proteins and the TCL-1 protein of SEQ ID NO: 2 share a similar epitope, both the claimed proteins and the TCL-1 protein of SEQ ID NO: 2 could be used to generate antisera that necessarily recognizes the shared epitope. Using the teachings of the specification for generation of antisera (page 58, lines 16-24), and immunoassays (page 40, line 25 to page 41, line 8), one of ordinary skill in the art could use the claimed proteins, with epitopes similar to TCL-1 epitopes, to generate antisera and test the antisera for binding to the TCL-1 protein of SEQ ID NO: 2. Therefore, using the claimed proteins, one skilled in the art could readily make and test antisera that would necessarily recognize the TCL-1 protein, without undue experimentation.

The Examiner stated that the claimed proteins "encompass a broad genus of proteins" and that "there is no teaching in the instant specification for how one would make and use [the claimed proteins]." (7/27/04 Office Action at 4). However, to enable a broad genus of compounds, a specification only needs to support one use that reasonably correlates with the entire scope of the claims. MPEP § 2164.01(c). All of the claimed proteins share the structural characteristic of a percent identity to SEQ ID NO: 2, and share the functional characteristic of binding to an antibody which also binds the TCL-1 protein of SEQ ID NO: 2. No protein that has both the structural and functional characteristics of the subject claim would lack an epitope for binding an antibody which also binds the TCL-1 protein of SEQ ID NO: 2. Thus, the genus of proteins claimed all have an epitope for binding an antibody which also binds TCL-1. Because, as presented above, the specification adequately supports making, testing and using the claimed proteins for generating antisera that recognizes TCL-1, and all of the claimed proteins have an eptitope that would be useful to generate that antisera, the specification supports a use of the claimed proteins across the scope of the claims.

Because the specification teaches how to make and use the proteins of the subject claims without undue experimentation, claims 18 and 19, as amended, are enabled. Reconsideration and withdrawal of the rejection is respectfully requested.

Response to rejection of claim 7 under 35 U.S.C. § 112, first paragraph, written description.

The Examiner rejected claim 7 in the 1/16/01 Office Action as failing to comply with the written description requirement, and maintains that rejection in the 7/27/04 Office Action. In the 1/16/01 Office Action, the Examiner stated that the "specification does not clearly describe the lower limit for what constitutes a fragment of the polypeptide of SEQ ID NO: 2."

The originally filed specification states that "[t]he invention provides fragments of a TCL-1 protein [SEQ ID NO: 2] consisting of at least 10 amino acids...." at page 10, lines 6-7. Therefore, the specification explicitly describes a lower limit for a fragment of the polypeptide of SEQ ID NO: 2.

In the 7/27/04 Office Action the Examiner alleged that the antibody that binds the fragment of claim 7 is not sufficiently defined, and thus, a skilled artisan could not envision the fragments that could be bound by an undefined antibody. While Applicants do not agree with the Examiner, claim 7 has been amended in an earnest effort to advance prosecution of the instant application, to further define the antibody as one which also binds to the TCL-1 protein of SEQ ID NO: 2. One of ordinary skill in the art would envision the fragments of claim 7 as being those that bind an antibody that also binds the TCL-1 protein of SEQ ID NO: 2.

Since the fragment of the TCL-1 protein recited in claim 7, as amended, is properly described through size and function, the written description requirement is fulfilled. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Based on the foregoing, all claims are believed to be in condition for allowance. An early and favorable action toward that end is earnestly solicited.

Respectfully submitted,

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